K062401
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510(k) SUMMARY

Jolife's Modified LUCAS®

This document provides a brief summary of the LUCAS® device and its supporting information.

1) GENERAL DATA

SEP 28 2006

510(k) submitter

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Contact person

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Columbia Square
555 Thirteenth street NW
Washington DC 20004-1109

Phone: (202) 637-5600

Date when prepared

August 7, 2006

Trade name

LUCAS

Common name

Mechanical chest compressor

Classification name

External cardiac compressor

Product code

DRM

Predicate devices

- Lucas (K053403)
- Thumper model 1007 (K972525)
- Autopulse model 100 (K040453)

2) DESCRIPTION OF THE DEVICE

LUCAS® is a pneumatically powered mechanical chest compression system providing controlled automated chest compressions on adult patients who have acute circulatory arrest.

LUCAS® consists of an upper part containing a pneumatically driven piston rod, which acts on the patients chest via a pressure pad integrated into the suction cup.

The support legs of the upper part are fastened to the back plate prior to starting compressions.

LUCAS® is powered by compressed air from a wall outlet in a hospital or an ambulance, or from a cylinder.

LUCAS® is designed to provide:

- Effective, consistent and uninterrupted compressions according to the guidelines given by the American Heart Association (AHA).
- Good circulation during the patient transport process.
- Safety during transportation for both personnel and patient, allowing emergency medical personnel to wear safety belts during transportation while LUCAS delivers continuous, consistent and uninterrupted compressions.
- Hands-free compressions in any situation.

LUCAS® can be applied to the patient in less than 20 seconds.

3) INTENDED USE / INDICATIONS FOR USE

LUCAS® External Cardiac Compressor is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS® must only be used in cases where manual chest compression would be used.

LUCAS® is only intended for temporary use.

4) COMPARISON TO PREDICATE DEVICES

LUCAS®, as well as the predicate devices, are able to provide chest compressions according to the guidelines given by the AHA.

LUCAS® and Thumper are acting and functioning in the same way based on a pneumatically powered device equipped with a compression pad on a piston.

Autopulse provides chest compressions based on an electrically powered device where the compression pad is a part of a circumferential belt.

5) SUMMARY OF SUBSTANTIAL EQUIVALENCE

The comparison in this submission demonstrates that LUCAS® is substantially equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

6) TESTING

Appropriate product testing was conducted and included a number of function tests during different operating conditions. These tests demonstrated that the functionality, safety and capability of LUCAS® comply with the product specifications and support substantial equivalence to predicate devices.

In all instances, the LUCAS® functioned as intended and all results observed were as expected.

Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Date: August 28, 2006

Reviewer: Catheirne Wentz

510(k) Number: K062401

Device Name: JoLife LUCAS External Cardiac Compressor

Reason for Conversion: This application for a CPR aid device, was submitted as a special. The modifications made to the device (addition of active decompression) constitutes a change in fundamental scientific technology as compared to the predicate [compression only] device. Prior to clearance of their predicate device (K053403), the sponsor received an NSE due to the active decompression component of the device. Active decompression has been determined to require clinical data due to the potential hemodynamic effects of active decompression. The predicate device (K053403) contains a suction cup which the sponsor put holes in to "deactivate" the decompression component of the device. This special serves to notify the FDA that the sponsor now wishes to eliminate the holes, thus returning the device to it's original design. The sponsor does state that the active decompression component will be limited to 3lbs, however, the active decompression component is a fundamental scientific change in technology as compared to the predicate [compression only] device.

Division Director Concurrence/Name: (Please get this before calling or e-mailing POS)

Date of POS Concurrence (please document POS contact):

Date of Phone Conversation:

*****Please add this to the file**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2006

Jolife AB
c/o Mr. Howard M. Holstein
Hogan & Hartson LP
555 13th Street, NW
Washington, DC 20004

Re: K062401
JoLife LUCAS External Cardiac Compressor
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III (three)
Product Code: DRM
Dated: August 16, 2006
Received: August 16, 2006

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K062401

Device Name: LUCAS®

Indications for Use:

LUCAS® External Cardiac Compressor is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS® must only be used in cases where manual chest compression would be used.

LUCAS® is only intended for temporary use.

Prescription Use __X__ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062401